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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/710,710	07/29/2004	Stanley C. Antosh	41260.003	4709

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EXAMINER	
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ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/710,710	ANTOSH ET AL.	
	Examiner	Art Unit	
	JOSEPH S. KUDLA	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Foreword

1. Applicants' Amendment-After Non-Final Rejection, Terminal Disclaimer, amended claims, Rule 1.131 affidavit by Stanley Antosh and amended specification, filed June 3, 2008, are acknowledged. With respect to Applicants' Arguments/Remarks in the correspondence, the arguments and request for reconsideration have been fully considered and are found to be partly persuasive. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and objection are newly applied. They constitute the complete set presently applied to the instant specification. This action is **NON-FINAL**.

Claims 1-30 are cancelled and new instant claims 31-60 are added.

Instant claims 31-60 are presented for examination on the merits as they read upon the elected subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(New Rejection precipitated by Applicants' Amendment)

2. Claims 31-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear from Applicant's instant claim set as to what the method is? The Examiner is confused as to whether the method is a method treating, a method of administering, a method of improving, etc. The lack of a clear method renders the claims indefinite.

Appropriate action is required.

(New Rejection precipitated by Applicants' Amendment)

3. Claims 48-49 and 59-60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims "creatine analogs." Because the instant specification does not provide written description or give examples of what structures are meant for such "creatine analogs," the phrase "creatine analogs" lacks adequate written description.

Regarding the requirement for adequate written description of chemical entities, Applicants' attention is directed to MPEP § 2163. In particular, *Regents of the University of California v. Eli Lilly & Co.*, 119 F. 3d 1559, 1568 (Fed. Cir. 1997), *cert denied*, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a

precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish list or plan for obtaining the claimed chemical invention." Eli Lilly, 119 F. 3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications under the U.S.C. 112.1 "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including *inter alia*, "functional characteristics when coupled with a known or disclosed correlation between function and structure..." *Enzo Biochem Inc. v. Gen-Probe Inc.*, 296 F. 3d 316, 1324-25 (Fed. Cir. 2002) (quoting *Guidelines*, 66 Fed. Reg. At 1106 (emphasis added)). Moreover, although *Eli Lilly* and *Enzo* were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. *Univ. of Rochester v. G.D. Searle & Co.*, 249 Supp. 2d 216, 225 (W.D.N.Y. 2003).

Applicant has failed to provide any written description for "creatine analogs" in the instant specification. As such, it is not apparent that Applicant was actually in possession of, and intended to use, within the context of the present invention, any creatine analogs of any of the compounds found within the instant specification, at the time the present invention was made.

Appropriate action is required.

Claim Rejections - 35 USC § 102

(New rejection)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 31-40, 42, 44, 46, 50, 51, 53, 55 and 57 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by **Beale et al. (US Patent 5,716,926)**.

The instant invention claims a method increasing cell energy production, muscle energy production muscle respiration and performance via the administration of methyl pyruvate or pyruvic acid. The instant invention claims administration routes, dosage forms, dosage amounts and salts of methyl pyruvate or pyruvic acid. The instant invention claims methods utilizing pyruvate or pyruvic acid with creatine compounds or with creatine compounds and a coenzyme.

Beale et al. teach the term “pyruvate” means any salt or ester of pyruvic acid (column 2, lines 28-30). Beale et al. teach specific forms of pyruvate useful are sodium pyruvate, calcium pyruvate and pyruvate substrates, such as pyruvyl-alanine, *inter alia* (column 5, lines 33-40). Beale et al. teach that the method enhances performance and/or endurance (Abstract and column 9, lines 7-10). Beale et al. teach the administration route can be oral (column 6, line 13) or parenteral (column 3, lines 22-23), the dosage form can be a liquid, pill, tablet *inter alia* (Abstract) and the amount to be administered is between 1-300 grams of the pyruvate-anabolic protein composition

wherein the pyruvate is 15% of the mixture (column 5, lines 26-28 and column 7, line 65). Beale et al. teach the pyruvate can be administered as a pharmaceutically acceptable mixture or incorporated in a foodstuff (column 8, line 60 to column 9, line5).

Instant claims 31 and 32 are anticipated because Beale et al. teach that “pyruvate" includes any of the salts or esters of pyruvate which includes pyruvic acid and methyl pyruvate coupled with the fact that the reference teaches increased performance via the administration of a composition comprising pyruvate. Instant claims 33 and 34 are anticipated by the administration of a composition comprising pyruvate, whether in the form of pyruvic acid or methyl pyruvate will inherently increase the concentration of these compounds in the body. Instant claims 35 and 36 are anticipated because Beale et al. teach oral and parenteral administration routes. Instant claims 37-39 and 50 are anticipated because Beale et al. teach the sodium and calcium salts of pyruvate and a pyruvate substrate. Instant claims 40 and 51 are anticipated because Beale et al. teach composition can be in a dosage that contains pharmaceutically acceptable excipients. Instant claims 42, 44, 53 and 55 are anticipated because Beale et al. teach a pharmaceutical drug for oral administration and a dietary supplement, such as a foodstuff. Instant claims 46 and 57 are anticipated because Beale et al. teach a 15% pyruvate composition in which 1-300 grams of the composition is administered (*e.g.*, 15% of 1 gram is 150 mg).

Claim Rejections - 35 USC § 103

(New rejections)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Beale et al. (US Patent 5,716,926)** as applied to claims 31-40, 42, 44, 46, 50, 51, 53, 55 and 57 above, and further in view of **Anelli et al. (US Patent 6,242,490)**.

The instant invention claims a method increasing cell energy production, muscle energy production muscle respiration and performance via the administration of methyl pyruvate or pyruvic acid. The instant invention claims administration routes, dosage forms, dosage amounts and salts of methyl pyruvate or pyruvic acid. The instant invention claims methods utilizing pyruvate or pyruvic acid with creatine compounds or with creatine compounds and a coenzyme.

Beale et al. teach the term "pyruvate" means any salt or ester of pyruvic acid (column 2, lines 28-30). Beale et al. teach specific forms of pyruvate useful are sodium pyruvate, calcium pyruvate and pyruvate substrates, such as pyruvyl-alanine, *inter alia* (column 5, lines 33-40). Beale et al. teach that the method enhances performance and/or endurance (Abstract and column 9, lines 7-10). Beale et al. teach the administration route can be oral (column 6, line 13) or parenteral (column 3, lines 22-23), the dosage form can be a liquid, pill, tablet *inter alia* (Abstract) and the amount to be administered is between 1-300 grams of the pyruvate-anabolic protein composition wherein the pyruvate is 15% of the mixture (column 5, lines 26-28 and column 7, line 65). Beale et al. teach the pyruvate can be administered as a pharmaceutically acceptable mixture or incorporated in a foodstuff (column 8, line 60 to column 9, line5).

Please see the 35 USC 102(b) rejection *supra* for the rejection of instant claims 31-40, 42, 44, 46, 50, 51, 53, 55 and 57.

Beale et al. does not teach the use of a creatine compound with the pyruvate compound in a method of increasing cell energy production, muscle energy production muscle respiration and performance.

Anelli et al. teach that creatine improved energy metabolism at the muscular level and exercise capacity of patients (column 1, lines 63-66).

It would have been obvious to one of ordinary skill in the art that since pyruvate as taught by Beale et al. is associated with increased performance and endurance and creatine as taught by Anelli et al. is associated with increased endurance and muscle energy production, that a combination of the two compounds in a method would also be

useful in increasing muscle energy and performance, thus rendering instant claim 48 obvious. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted).

6. Claims 41, 43, 45, 47, 52, 54, 56 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Beale et al. (US Patent 5,716,926)** as applied to claims 31-40, 42, 44, 46, 50, 51, 53, 55 and 57 above, and further in view of **Fantuzzi (US Patent Application 2006/0013888)**.

The instant invention claims a method increasing cell energy production, muscle energy production muscle respiration and performance via the administration of methyl pyruvate or pyruvic acid. The instant invention claims administration routes, dosage forms, dosage amounts and salts of methyl pyruvate or pyruvic acid. The instant invention claims methods utilizing pyruvate or pyruvic acid with creatine compounds or with creatine compounds and a coenzyme.

Beale et al. teach the term "pyruvate" means any salt or ester of pyruvic acid (column 2, lines 28-30). Beale et al. teach specific forms of pyruvate useful are sodium pyruvate, calcium pyruvate and pyruvate substrates, such as pyruvyl-alanine, *inter alia* (column 5, lines 33-40). Beale et al. teach that the method enhances performance and/or endurance (Abstract and column 9, lines 7-10). Beale et al. teach the

administration route can be oral (column 6, line 13) or parenteral (column 3, lines 22-23), the dosage form can be a liquid, pill, tablet *inter alia* (Abstract) and the amount to be administered is between 1-300 grams of the pyruvate-anabolic protein composition wherein the pyruvate is 15% of the mixture (column 5, lines 26-28 and column 7, line 65). Beale et al. teach the pyruvate can be administered as a pharmaceutically acceptable mixture or incorporated in a foodstuff (column 8, line 60 to column 9, line5).

Please see the 35 USC 102(b) rejection *supra* for the rejection of instant claims 31-40, 42, 44, 46, 50, 51, 53, 55 and 57.

Beale et al. does not teach the use of a coenzyme with the pyruvate compound in a method of increasing cell energy production, muscle energy production muscle respiration and performance.

Fantuzzi teaches methods of delivery of coenzyme Q10 (Abstract) wherein the agent is essential for the production of cellular energy (page 1, paragraph 3). Fantuzzi teaches the coenzyme can be administered as a dietary supplement or pharmaceutical (page 1, paragraphs 10 and 13 and page 3, paragraphs 39 and 40) at a dose of 104.09 mg (page 4, Example 1 and 2).

It would have been obvious to one of ordinary skill in the art that since pyruvate as taught by Beale et al. is associated with increased performance and endurance and coenzyme Q10 as taught by Fantuzzi is associated with increased energy production, that a combination of the two compounds in a method would also be useful in increasing muscle energy, thus rendering instant claims 41 and 52 obvious. “It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be

useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted). It would have been obvious to one of ordinary skill in the art that since Fantuzzi taught the oral administration of a pharmaceutical or a dietary supplement, that instant claims 43, 45, 54 and 56 are rendered obvious. It would have been obvious to one of ordinary skill in the art that since Fantuzzi taught the coenzyme is administered at 104.09 mg, instant claims 47 and 58 are rendered obvious.

7. Claims 49, 59 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Beale et al. (US Patent 5,716,926) and Fantuzzi (US Patent Application 2006/0013888)** and further in view of **Anelli et al. (US Patent 6,242,490)**.

The instant invention claims a method increasing cell energy production, muscle energy production muscle respiration and performance via the administration of methyl pyruvate or pyruvic acid. The instant invention claims administration routes, dosage forms, dosage amounts and salts of methyl pyruvate or pyruvic acid. The instant invention claims methods utilizing pyruvate or pyruvic acid with creatine compounds or with creatine compounds and a coenzyme.

Beale et al. teach the term "pyruvate" means any salt or ester of pyruvic acid (column 2, lines 28-30). Beale et al. teach specific forms of pyruvate useful are sodium pyruvate, calcium pyruvate and pyruvate substrates, such as pyruvyl-alanine, *inter alia*

(column 5, lines 33-40). Beale et al. teach that the method enhances performance and/or endurance (Abstract and column 9, lines 7-10). Beale et al. teach the administration route can be oral (column 6, line 13) or parenteral (column 3, lines 22-23), the dosage form can be a liquid, pill, tablet *inter alia* (Abstract) and the amount to be administered is between 1-300 grams of the pyruvate-anabolic protein composition wherein the pyruvate is 15% of the mixture (column 5, lines 26-28 and column 7, line 65). Beale et al. teach the pyruvate can be administered as a pharmaceutically acceptable mixture or incorporated in a foodstuff (column 8, line 60 to column 9, line5).

Fantuzzi teaches methods of delivery of coenzyme Q10 (Abstract) wherein the agent is essential for the production of cellular energy (page 1, paragraph 3). Fantuzzi teaches the coenzyme can be administered as a dietary supplement or pharmaceutical (page 1, paragraphs 10 and 13 and page 3, paragraphs 39 and 40) at a dose of 104.09 mg (page 4, Example 1 and 2).

Please see the 35 USC 102(b) rejection *supra* for the rejection of instant claims 31-40, 42, 44, 46, 50, 51, 53, 55 and 57 and the 35 USC 103(a) rejection at 6 supra for the rejection of instant claims 41, 43, 45, 47, 52, 54, 56 and 58 .

Beale et al. in view of Fantuzzi does not teach the use of creatine with a coenzyme and the pyruvate compound in a method of increasing cell energy production, muscle energy production muscle respiration and performance.

Anelli et al. teach that creatine improved energy metabolism at the muscular level and exercise capacity of patients (column 1, lines 63-66).

It would have been obvious to one of ordinary skill in the art that since pyruvate

as taught by Beale et al. is associated with increased performance and endurance and Fantuzzi is associated with increased energy production and creatine as taught by Anelli et al. is associated with increased endurance and muscle energy production, that a combination of the three compounds in a method would also be useful in increasing muscle energy and performance, thus rendering instant claims 49, 59 and 60 obvious. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted).

No claims allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Kudla whose telephone number is (571) 270-3288. The examiner can normally be reached on 9am - 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Joseph S. Kudla/
Examiner, Art Unit 1611
September 14, 2008

/Sharmila Gollamudi Landau/

Supervisory Patent Examiner, Art Unit 1611